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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/887,703 | 03/29/2001 | Joseph L. DiCesare | 03141- P0349A | 3422 |

24126 7590 10/05/2004

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| EXAMINER |
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SNAY, JEFFREY R

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/887,703

Applicant(s)

DICESARE ET AL.

Examiner

Jeffrey R. Snay

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,10 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09132004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09-13-04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 6, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aronowitz in view of Kinoshita et al.

Aronowitz discloses a test device which comprises, referring to Figures 1 and 5, a sampling wand having a sampling swab (118) and an analysis structure (560) for receiving sample from the sampling swab. The analysis structure further includes a cylindrical reagent disk (575) which incorporates all the reagents necessary to perform the desired test for an analyte in the sample (see column 8, paragraph [0096]).

The device of Aronowitz differs from the claimed invention in that it fails to specify the reagent disk as comprising a porous, non-fibrous absorbent polymeric material, and further fails to specify the incorporation of reagents therein by a process of contacting with a solvent/reagent solution followed by removal of the solvent.

However, Aronowitz does disclose the use of a porous, non-fibrous absorbent polymeric material as the sample collection swab. Furthermore, Aronowitz describes at length numerous advantages obtained thereby, including preclusion of inadvertent sample contamination (paragraph [0008]), absorption capacity (paragraph [0024]), and selectivity for analytes of interest (paragraph [0014]). One of ordinary skill in the art

would have recognized these same attributes as being desirable in the sample receiving reagent disk, in the same manner as are desirable with respect to the sample receiving swab. Thus, it would have been obvious to the skilled artisan to form the reagent disk in Aronowitz from the same polyvinyl alcohol polymer as utilized for the sampling swab.

In this regard, Kinoshita et al are relied upon as further evidence that the use of a porous, absorbent polymer, such as polyvinyl alcohol, as a reagent support was known. See specifically column 3, lines 47-63 of Kinoshita et al. Kinoshita et al further teach the known method of reagent application to such materials as comprising contacting with reagent solution followed by drying (see column 6, 4th full paragraph). It is noted that the instant limitation regarding a method of reagent introduction suffices as a product by process type limitation. As such, the specific method steps claimed need not be expressed by the prior art so long as the resultant product is reasonably concluded to be the same. Nonetheless, Kinoshita et al make disclose the same method of fabrication as the instant claims.

6. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aronowitz in view of Kinoshita et al, as applied above, and further in view of Rosenblatt ('728).

The device of Aronowitz, as modified and described above, differs from the claimed invention in that it fails to specify the presently claimed physical properties associated with the absorbent polymer. However, both Aronowitz and Kinoshita et al disclose open cell, absorbent polyvinyl alcohol polymers as well suited for the intended

Art Unit: 1743

purpose. Aronowitz further teaches that the particular physical properties of such materials are readily controlled and optimized, including density, porosity and other physical properties in accordance with the needs of the contemplated use. See column 3, paragraph [0021]. Finally, Rosenblatt, the disclosure of which has been fully detailed in the last Office action, discloses a polyvinyl alcohol porous material which is known as useful for as a medical sponge. The specific material disclosed by Rosenblatt is identical with that taught by the instant specification as commercially available and having the now claimed properties. As such, it would have been obvious to one of ordinary skill in the art to select the polymeric material of Rosenblatt in the modified device of Aronowitz in view of the desirable absorption capabilities thereof, and such material would inherently have exhibited the now claimed physical properties.

7. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aronowitz in view of Kinoshita et al, as applied above, and further in view of Miller et al.

Aronowitz is silent as to the particular reagents employed in the disclosed reagent disk. Miller et al disclose the same reagent system as is presently claimed, such reagent system being incorporated into a polymeric reagent substrate by lyophilization, for the purpose of enabling detection of microbial contaminants. See particularly Miller et al at column 8, line 54, through column 9, line 62. It would have been obvious to one of ordinary skill in the art to utilize the reagent system of Miller et al in the reagent disk of Aronowitz in order to enable the detection of microbial contaminants in a collected sample.

Response to Arguments

8. Applicant's arguments with respect to claims 1-3, 6-7, 10 and 12-16 have been considered but are moot in view of the new ground(s) of rejection.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/887,703

Art Unit: 1743

Page 7

A handwritten signature in black ink, appearing to read 'J. Snay', with a long horizontal flourish extending to the right.

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs